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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,903	03/01/2004	Gust H. Bardy	1201.1102102	2624
21691	7590	07/12/2005	EXAMINER	
CROMPTON SEAGER AND TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			MULLEN, KRISTEN DROESCH	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/790,903

Applicant(s)

BARDY ET AL.

Examiner

Kristen Mullen

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/1/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date <u>6/4/04</u>.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____</p> |
|--|---|

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 48-50, 52, 54-59, 61-62, 64-67, 69, 71-75 and 77-78 are rejected under 35 U.S.C. 102(b) as being anticipated by Hauser et al. (5,385,574).

With respect to claims 48, 56-59, 64-65 and 72-75, Hauser et al. shows a cardioverter-defibrillator (10) comprising a subcutaneous electrically active canister that houses a source of electrical energy, a capacitor, and operational circuitry; a subcutaneous lead or electrode connected to the canister including a subcutaneous cardioversion electrode (28, 29) (Figs. 2, 5, 6) (Col. 2, lines 20-43)

Regarding claims 49-50 and 66-67, Hauser shows the subcutaneous lead further includes one or more sensing electrodes (28, 29, 36) and where the second sensing electrode is electrically insulated from and spaced from the first sensing electrode (Fig. 5).

With respect to claims 52 and 69, Hauser shows a first sensing electrode (36) located adjacent a distal end of the lead, a first cardioversion-defibrillation electrode (28) located proximal to the first sensing electrode and the second sensing electrode (29) located proximal to the first cardioversion-defibrillation electrode (28) (Fig. 6).

With respect to claims 54 and 71, Hauser shows the canister comprises one or more sensing electrodes (80) (Col. 7, lines 16-25).

Regarding claims 61-62, 77 and 78, Hauser shows a second subcutaneous lead (Fig. 6) including a second subcutaneous cardioversion defibrillation electrode (Col. 5, lines 51-59).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 51 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al (5,385,574) as applied to claims 50 and 67. Hauser further shows a first sensing electrode (36) located adjacent a distal end of the lead, a second sensing electrode (28) located proximal to the first sensing electrode (36), a first cardioversion-defibrillation electrode (29) located proximal to the second sensing electrode (28) (Fig. 6). Hauser fails to teach the second sensing electrode is located on the lead about 1 to about 10 cm proximal from the first sensing electrode. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify spacing of the electrodes as taught by Hauser with the specific spacing set forth above, since applicant has not disclosed that this spacing provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any spacing of the electrodes such as the spacing taught by Hauser for a subcutaneous lead used for defibrillating and sensing the heart

5. Claims 53 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al (5,385,574) as applied to claims 50 and 67. Hauser discloses the claimed invention except for second sensing electrode is located on the lead about 1 to about 10 cm proximal from the first

Art Unit: 3762

sensing electrode and the configuration includes a cardioversion-defibrillation electrode located on a distal end of the lead with a first sensing electrode and second electrode located proximal from the cardioversion-defibrillation electrode. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the electrode arrangement and spacing as taught by Hauser with the specific arrangement and spacing set forth above, since applicant has not disclosed that these arrangement and spacing provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any arrangement and spacing of the electrodes such as the arrangement and spacing taught by Hauser for a subcutaneous lead used for defibrillating and sensing the heart

6. Claims 60 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al (5,385,574) as applied to claims 48 and 64, and further in view of Bennett et al. (5,331,966). Dahl et al. and Anderson et al. are as explained before. Hauser further shows the subcutaneous electrode is provided with a sensing electrode. Although Hauser fails to show the canister is provided with at one or more sensing electrodes, attention is directed to Bennett et al which shows a canister is provided with at one or more sensing electrodes and means for selecting two sensing electrodes for m the sensing electrodes located on the canister. Bennett et al. teaches that the canister provided with at one or more sensing electrodes provides a leadless orientation specific insensitive means for receiving electrical signals from the heart (Col. 10, lines 52-64). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Hauser to include a canister is provided with at one or more sensing electrodes and selecting means in order to provide a leadless orientation specific insensitive means for receiving electrical signals from the heart.

Art Unit: 3762

7. Claims 63 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al (5,385,574). Although Hauser fails to shows an attachment member located at the distal end of the subcutaneous lead, it is well known in the art to use barbs, tine, corkscrews etc. to fix leads to tissue. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Hauser to include an attachment member located at the distal end of the subcutaneous lead, since it well known in the art to do so.

8. Claims 80-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dahl et al. (5,300,106) in view of Anderson et al. (5,447,521). Dahl (5,203,348) shows making a skin incision in the thoracic region of a patient; inserting a curved introducer through the skin to make a subcutaneous path in the thoracic region; implanting the lead into the subcutaneous path so that the electrode is disposed within the portion of the path; placing a canister subcutaneously at the skin incision point; and closing the incision (Figs .4-7; Col. 4, line 67- Col. 6, line 29). Although Dahl fails to show the canister is electrically active and delivering the cardioversion-defibrillation energy using the canister and the subcutaneous electrode serves as the opposite electrode from the canister, attention is directed to Anderson. Anderson explains that implanting a electrically active canister in the pectoral region near the heart can be used in place of a subcutaneous electrode, which results in a more efficient system leading to a smaller size defibrillator canister. Using an electrically active canister in place of a subcutaneous electrode also eliminates the possible breakage of the subcutaneous electrode and reduces the number of parts needed for implantation since the defibrillator case is a “free” electrode (Col. 2, lines 3-61). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Dahl with an electrically active canister defibrillator in the pectoral region as Anderson teaches in place of one of the subcutaneous

Art Unit: 3762

electrodes in the pectoral region since it would result in a more efficient system, a smaller size defibrillator canister, eliminates the possible breakage of the subcutaneous electrode and reduces the number of implanted parts since the defibrillator case is a "free" electrode.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 48-79 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21, 26, 28, 29, 31, 33, 34, 38, 45-48, 50, 54, 55, 57, 74-79, 81-87, 89, 90, 93-94, 108, 110, 112, 114-116 and 118-121 of U.S. Patent No. 6,721,597. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application are broader and are met by the narrower patent claims (the patent claims contain all the limitations of the present application claims).

11. Claims 80-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-8 and 19-20 of U.S. Patent No. 6,721,597. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application are broader and are met by the

Art Unit: 3762

narrower patent claims (the patent claims contain all the limitations of the present application claims).

12. Claims 83-85 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-13, 15 and 18 of U.S. Patent No. 6,721,597. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application are broader and are met by the narrower patent claims (the patent claims contain all the limitations of the present application claims).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bob Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

kdm



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